K002182

DEC 2 9 2000

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0	Submitter's Name:	AViTA International Corp
	Address:	9F, No. 78, Sec. 1, Kwang-Fu Rd., San-Chung, Taipei County, Taiwan, R.O.C.
	Phone:	001-886-2-85121568
	Fax:	001-886-2-85121347
	Contact:	Mr. Geo Lin, General Manager
2.0	Device Name:	**AViTA TS0/TS1 Infrared Ear Thermometer** Models TS-001,TS-002,TS-003 and TS-101,TS-102,TS-103
3.0	Classification:	Class II
4.0	Predicate Device:	1. Braun ThermoScan IRT 3020 One Seconds Ear Thermometer (K983295) 2. K-Jump Health Co., Ltd.'s Infrared Ear Thermometer, Model KI-8120 (K984551)
5.0	Device Description:	**AViTA TS0/TS1 Infrared Ear Thermometer** is a hand-held, non-sterile, reusable clinical thermometer intended for the determination of human temperature by radiation emitted via the human ear **(Tympanic Temperature).**
6.0	Intended Use:	The **AViTA TS0/TS1 Infrared Ear Thermometer** is intended for the intermittent measurement and monitoring of human body temperature, through the opening of auditory canal, by consumers in the home.
7.0	Performance Summary:	In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included ASTM E1965-98, IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **AViTA TS0/TS1 Infrared Ear Thermometer** have the same intended use and similar technological characteristics as the Braun ThermoScan IRT 3020 One Seconds Ear Thermometer (K983295) and K-Jump Health Co., Ltd.'s Infrared Ear Thermometer, Model KI-8120 (K984551). Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the **AViTA TS0/TS1 Infrared Ear Thermometer**, Models TS-001,TS-002,TS-003 and TS-101,TS-102,TS-103 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 9 2000

Avita International Corporation
C/O Mr. Allen Reich
Harvest Consulting Corporation
900 North Switzer Canyon Drive #142
Flaggstaff, Arizona 86001

Re: K002182
Trade Name: Avita TSO/TS1 Infrared Ear Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 4, 2000
Received: October 6, 2000

Dear Mr. Reich:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Gerald W. Shipley for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K002182

DEVICE NAME: **AViTA TS0/TS1 Infrared Ear Thermometer**
AViTA International Corp.

INDICATIONS FOR USE.

The **AViTA TS0/TS1 Infrared Earl Thermometer** is used for the intermittent measurement and monitoring of human body temperature , through the opening of auditory cannal (the human ear). It is a hand-held, non-sterile, resuable clinical thermometer.

The device is to used and installed by people exception of handicapped persons and children.

The device is to used in the ENVIRONMENT of room temperature & normal environment condition.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The-Counter V
(Per 21 CFR 801.109) (Optional Format)

Janine Lumbers for CXC
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002182